Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Dec 2021

The effect of probiotic Saccharomyces Bulardi on mental health, quality of life, fatigue, pain and indices of inflammation and oxidative stress in Multiple Sclerosis (MS)

Protocol summary

Study aim

Determination of the effect of probiotic Saccharomyces Bulardi on mental health, quality of life, fatigue, pain and indices of inflammation and oxidative stress in Multiple Sclerosis

Design

This study is a phase-1, 4-month two arm parallel concealed, randomized, double-blind, placebo-controlled clinical trial among 50 participants with multiple sclerosis. Participants will randomly be divided into two groups to take either probiotic supplements (n D 25) or placebo (n D 25).

Settings and conduct

Sampling in this study will be done in a non probable and available way. All participants will be enrolled in the study after description of the methods of study and obtaining written informed consent. General information will be collected using a demographic questionnaire. After taking blood samples from patients and evaluating study variables and randomly entering them into one of two groups, capsules are delivered to people for two weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: multiple sclerosis confirmed by a neurologist; no other chronic diseases; not pregnant; not consuming probiotic foods from a month before the study Exclusion criteria: acute gastrointestinal disease; acute and severe phase of MS

Intervention groups

First, all participants would be matched based on body mass index and age. Participants would be then randomly divided into two groups to take either probiotic supplements (n D 25) or placebo (n D 25) for 4 months. In the intervention group (n D 25), participants will receive a probiotic capsule daily for 4 months. The probiotic capsule are contained Saccharomyces Bulardi.

Main outcome variables

mental health; fatigue, quality of life; pain; inflammatory indices (hs-CRP); Oxidative stress (total antioxidant capacity; superoxide dismutase; Malondialdehyde)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161022030424N1**
Registration date: **2018-04-09, 1397/01/20**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-09, 1397/01/20**
Update count: **0**

Registration date

2018-04-09, 1397/01/20

Registrant information

Name

Neda Dolatkhah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 1928

Email address

dolatkhahn@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of probiotic Saccharomyces Bulardi on mental health, quality of life, fatigue, pain and indices of inflammation and oxidative stress in Multiple Sclerosis (MS)

Public title
The effect of probiotic Saccharomyces Bulardi in Multiple Sclerosis (MS)
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Having a disease for more than a year Multiple sclerosis confirmed by a neurologist No other chronic diseases Lack of mental illness Not pregnant Not consuming probiotic foods from a month before the study
Exclusion criteria:
Unwillingness to continue studying at each stage Consumption of any probiotic food during the study Acute gastrointestinal disease Antibiotic use during the study Acute and severe phase of MS
Age
From **20 years** old to **45 years** old
Gender
Both

Phase
1
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomizations will be conducted by an assistant using permuted block randomization method and stratified randomization will be used to match participants based on age and body mass index
Blinding (investigator's opinion)
Triple blinded
Blinding description
It would be impossible for research personnel involving with participants or analyzing the study results to adjust randomization or discern what product participants were receiving, ensuring true allocation concealment. The placebo is indistinguishable in color, smell and taste from the probiotic capsule.
Placebo
Used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Regional Ethics Committee for Research (Human Subjects Studies) Tabriz University of Medical Science
Street address
Emam Reza Hospital, Golgasht, Azadi Avenue.
City
Tabriz
Province
East Azarbaijan
Postal code
5163995479
Approval date
2017-10-02, 1396/07/10
Ethics committee reference number
IR.TBZMED.REC.1396.592

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
mental health
Timepoint
Determining mental health at the beginning of the study (before the intervention) and 2 and 4 months after starting the administration of probiotic or placebo supplementation
Method of measurement
General Health Questionnaire (GHQ-28)

2

Description
quality of life
Timepoint
Determining quality of life at the beginning of the study (before the intervention) and 2 and 4 months after starting the administration of probiotic or placebo supplementation
Method of measurement

SF-36 quality of life questionnaire

3

Description
pain
Timepoint
Determining pain at the beginning of the study (before the intervention) and 2 and 4 months after starting the administration of probiotic or placebo supplementation
Method of measurement
visual analogue scale

4

Description
fatigue
Timepoint
Determining fatigue at the beginning of the study (before the intervention) and 2 and 4 months after starting the administration of probiotic or placebo supplementation
Method of measurement
fatigue severity scale (FSS)

5

Description
hs-CRP inflammatory index
Timepoint
Determining hs-CRP inflammatory index at the beginning of the study (before the intervention) and 4 months after starting the administration of probiotic or placebo supplementation
Method of measurement
biochemical assay

6

Description
total antioxidant capacity (TAC)
Timepoint
Determining total antioxidant capacity (TAC) at the beginning of the study (before the intervention) and 4 months after starting the administration of probiotic or placebo supplementation
Method of measurement
biochemical assay

7

Description
superoxide dismutase (SOD)
Timepoint
Determining superoxide dismutase (SOD) at the beginning of the study (before the intervention) and 4 months after starting the administration of probiotic or placebo supplementation
Method of measurement
biochemical assay

8

Description
malondialdehyde (MDA)
Timepoint
Determining malondialdehyde (MDA) at the beginning of the study (before the intervention) and 4 months after starting the administration of probiotic or placebo supplementation
Method of measurement
biochemical assay

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Probiotic capsule containing 250 mg yeast of Saccharomyces bullaria (1010 CFU) and 100 mg of magnesium and lactose stearates daily after a meal, for 4 months manufactured by a TakGene Zist (Tehran, Iran)
Category
Treatment - Drugs

2

Description
Control group: Placebo capsule containing 100 mg of magnesium and lactose stearates daily after a meal, for 4 months manufactured by a TakGene Zist (Tehran, Iran)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Neda Dolatkhah
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Azadi, Golgasht
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Tabriz
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tabriz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Neda Dolatkhah
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
Nutrition
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available